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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/03/2002 2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,626

Applicant(s)

COURSON, JERRY L.

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-33 are pending and are under examination.

Information Disclosure Statement

No IDS is filed with this application.

Drawings

No drawings have been filed with the instant application.

Objections

The specification is objected to because of the following: The statement of deposit in the specification, page 37, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement in the specification must be amended to include the deposit accession number.

Claims 1, 17, and 19 are objected to for failing to recite complete Accession information. The ATCC Accession No. must be filled in as appropriate.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

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failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6 " wherein said plant is male sterile" renders the claim indefinite because the plant of claim 2 is not a male sterile.

In claim 8, "A" should be changed to ---The---, and "the" before "cells" be deleted, for proper dependency. Also, "protoplasts of the tissue culture" is inconsistent with claim 7 which recites "tissue culture of regenerable cells".

In claims 10, 24, and 30 are indefinite in the recitation of "using" and "utilizing" of a composition without any active or positive steps.

In claims 13-14, "said corn plant" should be changed to --- the hybrid corn plant-- -, for clarification.

In claim 15, it is unclear how "different" the plants are. Would they be "genetically different", or otherwise? Dependent claim 16 is included in the rejection.

In claim 16, "said hybrid corn seed" should be changed ---the hybrid corn seed--.

In claim 17, ---corn seed---, should be inserted before "KW4636" in line 1, for clarification.

In claims 19-25, "KW4636-derived corn plant" renders the claims indefinite as it is unclear what is being retained in the derivative or the derived plant.

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Claims 19-25, and 29 are indefinite in the recitation of excellent, "early....." "above average.....", which are relative terms lacking a comparative basis. Also, the metes and bounds of "adapted to" are unclear.

In claims 26-27 the metes and bounds of a "transgene" are unclear as the term does not carry with it any limitations as to the structural or physiological properties of the gene.

In claim 31, "The corn breeding program of claim 30" lacks antecedent basis because claim 30 is drawn to a method rather than a corn breeding program.

Claim 27 is indefinite as the claimed method does not result in "a corn plant that contains its genetic material...transgenes". Dependent claim 28 is included in the rejection.

Claim 28 is indefinite because it is unclear if "corn plants are produced in claim 27. In addition, the limitation "corn plants" lacks antecedence in claim 27 which is drawn to a method for producing "a corn plant".

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "single gene conversion", in claim 33, is used by the claim to mean "moving a desired morphological and physiological characteristic via the backcrossing technique or via genetic engineering," (see page 8, paragraph 20 of the specification) while the accepted meaning is "a nonreciprocal

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event that occurs at or near the crossover point during reciprocal recombination." (see Darnell *et al* 1990, In Molecular Cell Biology, Scientific American Books, Inc. New York, New York, specifically page 478). The use of the term -- transgene -- would obviate this rejection.

Claim 33 is indefinite for reciting the improper Markush group of "resistance to bacterial, fungal or viral disease" which should have been recited as ---resistance to bacterial disease, resistance to fungal disease, resistance to viral disease---. Also, "corn endosperm or quality" is not a characteristic. Correction and/or clarification is required

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of the 35 U.S.C. 112, 1st paragraph may be satisfied by a

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deposit of the seed. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 37 of the specification indicating Applicants' intention to make an enabling deposit of the claimed invention with the ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for an enablement purpose.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and that the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808. See 37 CFR 1.809 for additional explanation of these requirements.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

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(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and,

(e) the deposit will be replaced if it should ever become unviable.

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for producing inbred corn seed KW4636, KW4636-derived or further-derived corn plants. However, the specification does not disclose a repeatable process to reproduce the claimed inbred seed KW4636. Therefore, a person skilled in the art would not be able to practice the claimed invention without undue experimentation.

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Claim Rejections - 35 USC § 112, Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-28 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are drawn to a corn plant or parts thereof of the inbred line KW4636 comprising a single gene conversion including transgenes which confer specific traits, or which have been transformed so that its genetic material contains one or more transgenes operably linked to regulatory sequences. The claims are also drawn to a method for producing an F1 plant that contains in its genetic material a transgene by crossing a transformed inbred corn line RII1 that contains the transgenes with an unidentified corn line or with a non-transformed inbred corn line KW4636, and corn plants and parts thereof produced by said method.

Applicant has not disclosed or provided guidance for a transformed or non-transformed corn inbred line KW4636 or parts thereof comprising a single gene conversion that confers specific characteristics, wherein such characteristics were

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transferred by breeding techniques. No guidance has been provided for the obtention of F1 generation or subsequent generation corn plants that retain any morphological or physiological characteristics of the inbred corn line RII1, in addition to a single gene conversion or transferred transgenes.

While the transformation of a plant with a transgene that confers a desired trait such as herbicide resistance, insect resistance, resistance to pathogens, or male sterility, is well within the level of one skilled in the art, the state of the art teaches that it is unpredictable whether a gene or genes for conferring a phenotype in one plant genotypic background may be transferred into the genetic background of another plant to confer the phenotype in said different plant. For example, Hunsperger et al (US Patent No. 5, 523, 520) disclosed a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species, that didn't result in the expected transfer gene trait (column 3, lines 26-46). Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and that such effects are unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). See also, Eshed et al who teach that in plants,

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epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides evidence that such linkage disequilibrium, linkage drag, or epistatic effects are not common in corn breeding materials, such that one or more single gene traits can be transferred from one genetic background to another.

Therefore, given the lack of guidance in Applicants specification regarding single gene conversion in corn inbred line KW4636, the lack of guidance regarding the isolation of a multitude of non-exemplified transgenes or their evaluation in particular corn genetic backgrounds, the state of the art, the unpredictability inherent in single gene conversion, and lack of working examples, one skilled in the art would not be able to make a transformed corn inbred line KW4636 or parts thereof further comprising a single gene conversion, or KW4636-derived plants including F1 and subsequent generation plants that retain any KW4636-derived morphological or genetic characteristics, without undue experimentation. Applicants should note that no single gene conversion plant or plants with any of the phenotype of claim 33 have been disclosed. Applicants should also note that one skilled in the art would not be able to make and/or use a corn plant or parts thereof that are not adequately described (see Written description rejection below).

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Written Description

Claims 12-16 and 19-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines.

Claims 12-16 are drawn to hybrid corn seeds/plants or F1 generation plants produced from crossing two inbred parent corn plants, wherein the identity of only one of the parent plant is known to be KW4636 inbred corn plant, and the other parent plant is unknown.

Applicant has not described all of the F1 generation plants, in terms of their morphological and physiological characteristics. While the specification discloses unique morphological and physiological characteristics of the inbred corn line KW4636, the claims are not limited to those F1 generation plants that retain all of the morphological and physiological characteristics of the inbred corn plant KW4636. Moreover, no genetic markers unique to KW4636 and which are maintained in the progeny plants have been disclosed.

Claims 19-25 and 29-32 are drawn to KW4636-derived or further derived corn plants of undisclosed number of generations having unknown identifying characteristics, wherein inbred line KW4636 might be utilized only in the first

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generation cross, and methods for producing said plants. The specification only discloses a single inbred corn line, KW4636 with specified characteristics. These are genus claims. There are insufficient relevant identifying characteristics which would allow one skilled in the art to predictably determine the genomic structure or the phenotypic characteristics of the plant obtained at each level of crossing or at each generation, absent further guidance. In addition, the breeding techniques produced by said plants encompass recurrent selection, mass selection, bulk selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic markers enhanced selection, and transformation. Each of these breeding techniques would result in a phenotypically different plant. Therefore, substantial variation in morphological and physiological characteristics is expected among the species of the claimed genus. The only characteristics disclosed for the plants are the expression of the combination of at least two traits which are described with relative terms that lack comparative basis (see the rejection under 35 USC, 112, 2nd paragraph). Since no identifying characteristics have been disclosed even for the F1 generation plants, the characteristics of subsequent outcrossed generations have similarly not been described. Therefore, one skilled would not recognize from the disclosure that Applicants are in possession of the invention as broadly claimed.

Claims 26-28 are drawn to inbred corn plants KW4636 or hybrid corn plants comprising one or more transgenes or single gene conversion that confers specific

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characteristics and a method. However, since Applicant has not described the specific chemical or physical characteristics of all transgenes or the phenotypic characteristics of plants transformed therewith, one skilled in the art would not recognize from the specification that Applicants were in possession of the invention as broadly claimed at the time the invention was made.

The Federal Circuit court stated that a written description of an invention “requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material.” *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material”. *Id.* Further, the court held that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of members of the genus”. *Id.*

In the instant case, the disclosure of a single corn inbred line, KW4636, does not provide an adequate written description for the claimed genus, hybrid corn plants/seeds, KW4636-derived or further derived corn plants, wherein only one parent is known or where only one ancestor of the plant is known to be KW4636, and the rest of the ancestors are unknown. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See

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Written Description Requirement published in Federal Registry/Vol. 66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

Claims 12-16, 19-25 and 27-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Foley (US Patent 5,973, 239, filed 12/04/1998(A)).

Foley disclosed an inbred corn plant/seed designated as LH265 with characteristics such as above average stay green, above average pollen shed, good yield, stalk quality, resistance to diseases, normal starch endosperm, and is adapted to north-central regions. Foley also teaches methods for producing a corn plant and seeds by crossing the inbred corn line LH265 with itself or with another corn line as well as hybrid corn plant and seeds produced by crossing the inbred line LH265 with another corn line. Foley also disclosed the corn inbred line may further comprise a cytoplasmic factor that confers male sterility or may comprise a single gene conversion that will characteristics such as herbicide resistance, resistance to insects, resistance to bacterial diseases, fungal diseases, viral disease, or enhanced endosperm quality. The reference also teaches a method for producing a progeny plant having a transgene. Since the prior art corn plant and the claimed corn plant share characteristics such as a cytoplasmic factor that confers male sterility or a single gene conversion that will confer characteristics such as herbicide resistance, resistance to

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insects, resistance to bacterial diseases, fungal diseases, viral disease and enhanced endosperm quality, the claimed hybrid corn plant/ seeds are expected to possess such characteristics, especially since the second parents involved in the breeding are not known. While the corn plant of Foley is designated as LH265 and the corn inbred line of the instant invention is designated as KW4636, there are insufficient identifying characteristics set forth in the claims that distinguish the claimed corn plant from the prior art corn plant. Also, the claim languages "excellent", "early", "above average", and "adapted to" are relative terms lacking a comparative basis (as indicated in 112, 2nd paragraph rejection), the claimed agronomic traits are considered to be identical to those of the prior art

It would have been *prima facie* obvious to an ordinary plant breeder at the time of Applicants invention to use the method disclosed by Foley with any corn plants/seeds to produce corn plants with characteristics such as male sterility, herbicide resistance, resistance to insects, resistance to bacterial diseases, to fungal diseases, or to viral disease, or corn seeds with enhanced endosperm quality.

Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art, absent evidence to the contrary.

Remarks

No claim has been allowed.

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Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

September 25, 2002

mai

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**